510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

FEB 2 5 2011

This summary of safety and effectiveness is provided as part of this Premarket Notification in compliance with 21 CFR, Part 807, Subpart E, Section 807.92.

1. Submitter's Information: 21 CFR 807.92(a)(1)

MEDISON CO., LTD. 1003, Daechi-dong, Gangnam-gu, Seoul 135-280, Korea

Contact Person:

Kyeong-Mi, Park Regulatory Affairs Manager

Telephone:

82.2.2194.1373

Facsimile:

82.2.556.9209

Data Prepared: August 12, 2010

2. Name of the device:

Common/Usual Name:

Diagnostic Ultrasound System and Accessories

Proprietary Name:

ACCUVIX XG Diagnostic Ultrasound System

Classification Names:	FR Number	Product Code
Ultrasonic Pulsed Doppler Imaging System	892.1550	IYN
Ultrasound Pulsed Echo Imaging System	892.1560	IYO
Diagnostic Ultrasound Transducer	892.1570	ITX

3. Identification of the predicate or legally marketed device:

K101455, EKO 7 Diagnostic Ultrasound System K092159, ACCUVIX V20 Diagnostic Ultrasound System

4. Device Description:

The ACCUVIX XG is a general purpose, mobile, software controlled, diagnostic ultrasound system. Its function is to acquire ultrasound data and to display the data as B mode, M mode, Color Doppler imaging, Power Doppler imaging, PW/CW Spectral Doppler mode, Harmonic imaging, Tissue Doppler imaging, 3D imaging mode (real time 4D imaging mode) or as a combination of these modes. The ACCUVIX XG also gives the operator the ability to measure anatomical structures and offers analysis packages that provide information that is used to make a diagnosis by competent health care professionals. The ACCUVIX XG has real time acoustic output display with two basic indices, a mechanical index and a thermal index, which are both automatically displayed.

The ACCUVIX XG has been designed to meet the following product safety standards:

- UL 60601-1, Safety requirements for Medical Equipment
- CSA C22.2 No. 601.1, Safety requirements for Medical Equipment
- IEC60601-2-37, Diagnostic Ultrasound Safety Standards
- EN/IEC60601-1, Safety requirements for Medical Equipment
- EN/IEC60601-1-2, EMC requirements for Medical Equipment
- NEMA UD-2, Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment
- NEMA UD-3, Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
- IEC 61157, Declaration of the acoustic output
- ISO10993-1, Biocompatibility

5. Intended Uses:

The ACCUVIX XG Diagnostic Ultrasound System and transducers are intended for diagnostic ultrasound imaging and fluid analysis of the human body.

The clinical applications include: Fetal, Abdominal, Intra-operative, Pediatric, Small Organs, Neonatal Cephalic, Adult Cephalic, Trans-rectal, Trans-vaginal, Muscular-Skeletal (Conventional, Superficial), Cardiac Adult, Cardiac Pediatric, Peripheral vessel.

6. Technological Characteristics:

The ACCUVIX XG is substantially equivalent to the ACCUVIX V20 Diagnostic Ultrasound System, cleared via K092159, and the EKO 7 Diagnostic Ultrasound System, cleared via K101455. All systems transmit ultrasonic energy into patients, then perform post processing of received echoes to generate onscreen display of anatomic structures and fluid flow within the body. All system allow for specialized measurements of structures and flow, and calculations.

END of 510(K) Summary



Food and Drug Administration 10903 New Hampshire Avenue Silver Spring, MD 20993

Medison Co., Ltd. % Mr. Mark Job Responsible Third Party Official Regulatory Technology Services LLC 1394 25th Street NW BUFFALO MN 55313

FEB 2 5 2011

Re: K103397

Trade/Device Name: ACCUVIX XG Diagnostic Ultrasound System

Regulation Number: 21 CFR 892.1550

Regulation Name: Ultrasonic pulsed doppler imaging system

Regulatory Class: II

Product Code: IYO, ITX, and IYN

Dated: February 8, 2011 Received: February 10, 2011

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the ACCUVIX XG Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

C1-4EC	<u>VR5-9</u>	<u>P2-4BA</u>	<u>V5-9</u>
C2-61C	<u>L3-8</u>	P3-8CA	<u>V6-12</u>
C4-9/10ED	L5-131S	<u>P4-12</u>	<u>CW2.0</u>
ER4-9/10ED	LF5-12	<u>3DC2-6</u>	<u>CW4.0</u>
EV4-9/10ED	LS5-13	<u>V4-8</u>	

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the <u>Federal Register</u>.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

If you have any questions regarding the content of this letter, please contact Paul Hardy at (301) 796-6542.

Sincerely Yours,

Mary Pastel, ScD.

Director

Division of Radiological Devices Office of In Vitro Diagnostic Device

Evaluation and Safety

Center for Devices and Radiological Health

Enclosure(s)

SECTION 1.3 INDICATIONS FOR USE

510(k) Number (if know	/n):	-		
Device Name: ACCU	VIX XG Diagnos	stic Ultrasound System	·	
Indications-for-Use;				
The clinical applications	sis of the numan to include: Fetal, A ectal, Trans-vagin	body. Abdominal Intra-operative	are intended for diagnostic u Pediatric, Small Organ, Nec aventional, Superficial), Car	
			•	
				,
Prescription Use (Part 21 CFR 801)	√ Subpart D)	AND/OR	Over-The-Counter t (21 CFR 801 Subpa	
(PLEASE DO 1	NOT WRITE BELO	OW THIS LINE-CONTINUE	ON ANOTHER PAGE OF N	EEDED)
- Cc	oncurrence of CD	PRH, Office of In Vitro Dia	gnostic Devices (OIVD)	
		May SPa	LI.	
Indications for Use	, Office ((Division Sign-Off) Division of Radiological Device of In Vitro Diagnostic Device East	es .	Section 1.3, page 1

510(k) No.:

Device Name: ACCUVIX XG Diagnostic Ultrasound System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application						cludes simultaneo	
General (Track Lonly)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							\-
<u> </u>	Fetal (See Note 3)	И	N	N		N	Note I	Notes 2, 7, 8
	Abdominal	N	N	N	N	N	Note I	Notes 4, 7
	Intra-operative (See Note 6)	N	Ν	N	-	N	Note I	Notes 8, 9
	Intra-operative (Neuro.)	N	N	N		N	Note I	Notes 8, 9
Fetal Imaging	Laparoscopie	1						
& Other	Pediatric	N	N	N		N	Note I	Note 2, 5, 6, 7, 8, 9, 10
	Small Organ (See Note 5)	N	N	N		N	Note I	Note 2, 5, 6, 7, 8, 9, 10
	Neonatal Cephalic	N	N	N.		N	Note I	Note 2, 7, 8, 9
	Adult Cephalic	N	N	N	N	N	Note I	Note 4, 7
	Trans-rectal	N	Ν	N		N	Note I	Note 2, 7, 8, 10
	Trans-vaginal	N	N	N		N	Note I	Note 2, 7, 8, 10
	Trans-urethral					<u> </u>		11010 2, 7, 0, 10
	Trans-esoph. (non-Cardiac)	1					· · · · · · · · · · · · · · · · · · ·	<u> </u>
	Musculo-skel. (Convent.)	N	N	N		N	Note I	Note 2, 5, 6, 7, 8, 9, 10
	Musculo-skel. (Superfic.)	N	N	N		N	Note I	Note 2, 5, 6, 7, 8, 9, 10
	Intra-luminal	 				<u> </u>	1000	1100 2, 3, 0, 7, 8, 9, 10
	Other (spec.)	1		<u> </u>	-			
	Cardiac Adult	N	N	N	N	N	Note I	Niete A 7
Cardiac	Cardiac Pediatric	N.	N	N	N	N	Note I	Note 4, 7 Note 4, 7
	Trans-esophageal (Cardiac)	1-						11010 7, 1
	Other (spec.)	1-						
Peripheral	Peripheral vessel	N	N	N	N	N	Note I	Note 2, 5, 6, 7, 9, 10
Vessel	Other (spec.)			T				11016 4, 3, 6, 1, 7, 10

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler
Note 1: B+M, B+PW, B+C, B+PD, B+CW, B+C+PW, B+PD+PW, B+C+M, Dual B, Dual B+C, Dual B+PD

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Note 10: ElastoScan

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD) Prescription Use (Per 21 CFR 801.109)

Indications for Use

Division of Madiological Devices Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) No.:

Device Name: C1-4EC for use with ACCUVIX XG

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application		Mode of Operation (*includes simultaneous B-mode)									
General (Track Lonly)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)				
Ophthalmic	Ophthalmic							Дорост				
	Fetal (See Note 3)	Р	Ρ	P		ρ	Note I	Notes 2, 7, 8				
	Abdominal	Р	Ρ	Р		P	Note I	Notes 2, 7, 8				
	Intra-operative (See Note 6)							110103 2, 7, 0				
	Intra-operative (Neuro.)							<u> </u>				
Fetal Imaging	Laparoscopic			<u> </u>								
& Other	Pediatric	Р	P	Р		Р	Note 1	Notes 2, 7, 8				
	Small Organ (See Note 5)	1					1100	140165 2, 7, 8				
	Neonatal Cephalic	—										
	Adult Cephalic	\neg										
	Trans-rectal	_										
	Trans-vaginal	1										
	Trans-urethral	1		 								
	Trans-esoph. (non-Cardiac)	\top		 								
	Musculo-skel. (Convent.)											
	Musculo-skel. (Superfic.)											
	Intra-luminal	1-						 				
	Other (spec.)	+-										
-	Cardiac Adult	1										
Cardiac	Cardiac Pediatric							· · · · · · · · · · · · · · · · · · ·				
	Trans-esophageal (Cardiac)											
	Other (spec.)	7						<u></u>				
Peripheral	Peripheral vessel				<u> </u>							
Vessel	Other (spec.)			 				·				

N= new indication; P= previously cleared by FDA K101455; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+CW, B+C+PW, B+PD+PW, B+C+M, Dual B, Dual B+C, Dual B+PD

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD) Prescription Use (Per 21 CFR 801.109)

Indications for Use

Division of Radiological Devices Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) No.:

Device Name: C2-6IC for use with ACCUVIX XG

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application						des simultaneous B-	
General (Track I only)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							(=
	Fetal (See Note 3)	Р	Р	Р		p	Note I	Notes 2, 7, 8
	Abdominal	Р	Р	Р	,	Р	Note I	Notes 2, 7, 8
	Intra-operative (See Note 6)			1				110103 2, 7, 0
	Intra-operative (Neuro.)							
Fetal Imaging	Laparoscopic	_			<u> </u>			
& Other	Pediatric	þ	P	P		P	Note 1	Notes 2, 7, 8
	Small Organ (See Note 5)						110101	140163 2, 7, 8
	Neonatal Cephalic							-
	Adult Cephalic	_						····
	Trans-rectal	1						
	Trans-vaginal	_		 				
	Trans-urethral	_						
	Trans-esoph. (non-Cardiac)	_					-	 .
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)	1		-				·
	Intra-luminal	+		-				
	Other (spec.)	_			·			
	Cardiac Adult	+		-		<u> </u>		
Cardiac	Cardiac Pediatric							
	Trans-esophageal (Cardiac)	$\dashv \neg \dashv$		\vdash				
	Other (spec.)	\dashv						
Peripheral	Peripheral vessel			-				
Vessel	Other (spec.)	1		\vdash	<u> </u>	 		<u></u> .

N= new indication; P= previously cleared by FDA K092159; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+CW, B+C+PW, B+PD+PW, B+C+M, Dual B, Dual B+C, Dual B+PD

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD) Prescription Use (Per 21 CFR 801.109)

Indications for Use

Division of Radiological Devices Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) No.:

Device Name: C4-9/10ED for use with ACCUVIX XG

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application				Mode of C	peration (*inclu	des simultaneous B	mode)
General (Track Lonly)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							Y=F==-/
	Fetal (See Note 3)	Р	Р	P		Р	Note I	Notes 2, 7, 8
	Abdominal	Р	Р	Р	-	Р	Note 1	Notes 2, 7, 8
	Intra-operative (See Note 6)					-	-	
	Intra-operative (Neuro.)							
Fetal Imaging	Laparoscopic	_			<u> </u>	 		
& Other	Pediatric	P	Р	р		Р	Note 1	Notes 2, 7, 8
	Small Organ (See Note 5)	Р	Р	Р		Р	Note 1	Notes 2, 7, 8
	Neonatal Cephalic	P	Р	Р		Р	Note I	Notes 2, 7, 8
	Adult Cephalic	_					-	7,0103 2, 7, 0
	Trans-rectal	1			·····	 		
	Trans-vaginal	\top	-	<u> </u>		 	 +	
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)	1				 		
	Musculo-skel. (Superfic.)]				
	Intra-luminal	┪~		1		 		
	Other (spec.)	1						
	Cardiac Adult	1						
Cardiac	Cardiac Pediatric	$\neg \neg$						
	Trans-esophageal (Cardiac)	1	T	 		 		
	Other (spec.)	\top						· ····
Peripheral	Peripheral vessel	Р	Р	Р		Р	Note I	Notes 2, 7, 8
Vessel	Other (spec.)	1				 		110(63 2, 7, 0

N= new indication; P= previously cleared by FDA K092159; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+CW, B+C+PW, B+PD+PW, B+C+M, Dual B, Dual B+C, Dual B+PD

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD) Prescription Use (Per 21 CFR 801.109)

Indications for Use

Division of Radiological Devices Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) No.:

Device Name: ER4-9/10ED for use with ACCUVIX XG

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as foll

	Clinical Application		Mode of Operation (*includes simultaneous B-mode)									
General (Track I only)	Specific (Tracks I & III)	B	М	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)				
Ophthalmic	Ophthalmic						(0,00.)	(эрес.)				
	l etal (See Note 3)	+-	_	 								
	Abdominal	1										
	Intra-operative (See Note 6)	1-										
	Intra-operative (Neuro.)	1-				 	··					
Fetal Imaging	Laparoscopic	\top		1		 						
& Other	Pediatric	\top										
	Small Organ (See Note 5)	 				 						
	Neonatal Cephalic			 		 						
	Adult Cephalic	1		 		 	·					
	Trans-rectal	Р	Р	Р		P	Note I	Note 2, 7, 8				
	Trans-vaginal	P	Р	P		Р	Note I					
	Trans-urethral	1	-				Note 1	Note 2, 7, 8				
	Trans-esoph. (non-Cardiac)	\dashv										
	Musculo-skel. (Convent.)	1-										
	Musculo-skel. (Superfic.)	1-		 								
	Intra-luminal			†	<u>.</u>							
	Other (spec.)					<u> </u>	 -					
	Cardiac Adult	\top										
Cardiac	Cardiac Pediatric	1-						- -				
	Trans-esophageal (Cardiac)											
	Other (spec.)				-	 						
Peripheral	Peripheral vessel	_										
Vessel	Other (spec.)					 						

N= new indication; P= previously cleared by FDA K092159; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+CW, B+C+PW, B+PD+PW, B+C+M, Dual B, Dual B+C, Dual B+PD

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes intertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD) Prescription Use (Per 21 CFR 801.109)

Indications for Use

(Division Sign-Off)
Division of Radiological Devices Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) No.:

Device Name: EV4-9/10ED for use with ACCUVIX XG.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follo

	Clinical Application	Mode of Operation (*includes simultaneous B-mode)									
General (Track Lonly)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)			
Ophthalmic	Ophthalmic						(Spec.)	(Spec.)			
	Fetal (See Note 3)	-		·		 					
	Abdominal			† —							
	Intra-operative (See Note 6)	1									
	Intra-operative (Neuro.)	_				 		·			
Fetal Imaging	Laparoscopic										
& Other	Pediatric					 					
	Small Organ (See Note 5)	_		 		 					
	Neonatal Cephalic	1				 					
	Adult Cephalic			 		 					
	Trans-rectal	1 p	P			Р	Note I				
	Trans-vaginal	Р	P	P		P		Note 2, 7, 8			
	Trans-urethral	-1	<u> </u>	-		 	Note I	Note 2, 7, 8			
	Trans-esoph. (non-Cardiac)		<u> </u>								
	Musculo-skel. (Convent.)	+									
	Musculo-skef. (Superfic.)		· ·								
	Intra-luminal	\dashv					<u> </u>				
	Other (spec.)					 					
	Cardiac Adult										
Cardiac	Cardiac Pediatric					 					
	Trans-esophageal (Cardiac)			-		 					
	Other (spec.)	1									
Peripheral	Peripheral vessel										
Vessel	Other (spec.)										

N= new indication; P= previously cleared by FDA K092159; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler
Note I: B+M, B+PW, B+C, B+PD, B+CW, B+C+PW, B+PD+PW, B+C+M, Dual B, Dual B+C, Dual B+PD

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Concurrence of CDRII, Office of In Vitro Diagnostic Devices (OIVD) Prescription Use (Per 21 CFR 801.109)

> (División Sign-Off) Division of Radiological Devices

Office of In Vitro Diagrostic Device Evaluation and Safety

Section 1.3, page 7

Indications for Use

510(k) No.:

Device Name: VR5-9 for use with ACCUVIX XG

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application						des simultaneous B	
General (Track Lonly)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic						(Брес.)	(зрес.)
	Fetal (See Note 3)	 						·
	Abdominal	\neg		1				
	Intra-operative (See Note 6)					 		
	Intra-operative (Neuro.)	1	_		<u> </u>			
Fetal Imaging	Laparoscopic	\neg		 				
& Other	Pediatric	1		 		<u> </u>	-	
	Small Organ (See Note 5)							
	Neonatal Cephalic	_		<u> </u>				
	Adult Cephalic			 				
•	Trans-rectal	N	N	N		N	Note I	No. 2 2 2 2 40
	Trans-vaginal	N	N	N	<u> </u>	N	Note 1	Note 2, 7, 8, 10
	Trans-urethral	\dashv	_	 -			Note 1	Note 2, 7, 8, 10
	Trans-esoph. (non-Cardiac)	\top						
	Musculo-skel. (Convent.)	1						
	Musculo-skel. (Superfic.)							
	Intra-luminal						 .	
	Other (spec.)							
	Cardiac Adult							· · · · · · · · · · · · · · · · · · ·
Cardiac	Cardiac Pediatric	1						
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral	Peripheral vessel			_				
Vessel	Other (spec.)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler
Note 1: B+M, B+PW, B+C, B+PD, B+CW, B+C+PW, B+PD+PW, B+C+M, Dual B, Dual B+C, Dual B+PD

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes intentility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Note10: ElastoScan

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD) Prescription Use (Per 21 CFR 801.109)

Indications for Use

(Division Sign-Off) Division of Radiological Devices Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) No.:

Device Name: L3-8 for use with ACCUVIX XG

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis

	Clinical Application				Mode of O	peration (*inclu	des simultaneous L	R-moda)
General (Track Fonly)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
	Fetal (See Note 3)							
	Abdominal	_						-
	Intra-operative (See Note 6)	\top		<u> </u>		 -		
	Intra-operative (Neuro.)	1					-	
Fetal Imaging	Laparoscopic	_		†——				
& Other	Pediatric	Р	Р	Р		Р	Note 1	Note 2, 5, 6, 7, 9
	Small Organ (See Note 5)	Р	P	Р		P	Note 1	Note 2, 5, 6, 7, 9
	Neonatal Cephalic						14016 1	Note 2, 3, 6, 7, 9
	Adult Cephalic	_						
	Trans-rectal	+		\vdash				
	Trans-vaginal							· · · · · · · · · · · · · · · · · · ·
	Trans-urethral			 				
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)	P	Р	4		P	Note 1	Note 2, 5, 6, 7, 9
	Musculo-skel. (Superfic.)	Р	Р	Р		P	Note 1	Note 2, 5, 6, 7, 9
	Intra-luminal							14010 2, 3, 0, 7, 9
	Other (spec.)	┪		 				
	Cardiac Adult	—						
Cardiac	Cardiac Pediatric							· · · · · · · · · · · · · · · · · · ·
	Trans-esophageal (Cardiac)	1						· · · · · ·
	Other (spec.)	1-						
Peripheral	Peripheral vessel	Р	Р	Р		P	Note I	Mary 3 5 4 7 ()
Vessel	Other (spec.)		•	 		·'	INULE I	Note 2, 5, 6, 7, 9

N= new indication; P= previously cleared by FDA K101455; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

- Note 1: B+M, B+PW, B+C, B+PD, B+CW, B+C+PW, B+PD+PW, B+C+M, Dual B, Dual B+C, Dual B+PD
- Note 2: Includes imaging for guidance of biopsy
- Note 3: Includes infertility monitoring of follicle development
- Note 4: Color M-mode
- Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients
- Note 6: Abdominal organs and peripheral vessel
- Note 7: Tissue Harmonic Imaging (THI)
- Note 8: 3D imaging
- Note 9: Panoramic imaging

Concurrence of CDRII, Office of In Vitro Diagnostic Devices (OIVD) Prescription Use (Per 21 CFR 801.109)

Indications for Use

(Division Sign-Off) Division of Radiological Devices

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) No.:

Device Name: L5-13IS for use with ACCUVIX XG

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application	Mode of Operation (*includes simultaneous B-mode)										
General (Track I only)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)				
Ophthalmic	Ophthalmic	\top					(5)60.)	(apec.)				
	Fetal (See Note 3)	+						 				
	Abdominal						· · · · · · ·	 				
	Intra-operative (See Note 6)			 -				 				
	Intra-operative (Neuro.)			†			<u>_</u>	 -				
Fetal Imaging	Laparoscopic											
& Other	Pediatric	P	Р	Р		p	Note I	Note 2, 5, 6, 7, 9, 10				
	Small Organ (See Note 5)	P	Р	4		P	Note I	Note 2, 5, 6, 7, 9, 10				
	Neonatal Cephalic			<u> </u>		 -	Note 1	140.6 2, 3, 6, 7, 9, 10				
	Adult Cephalic	_		 	_	 		 				
	Trans-rectal	 										
	Trans-vaginal	_		<u> </u>		 		 				
	Trans-urethral		-	<u> </u>				 				
	Trans-esoph. (non-Cardiac)	\top		 -								
	Musculo-skel. (Convent.)	P	Р	р		p	Note I	Note 2 5 6 7 0 10				
	Musculo-skel. (Superfic.)	Р	P	μ		P	Note I	Note 2, 5, 6, 7, 9, 10				
	Intra-luminal	_				- ' -	Note I	Note 2, 5, 6, 7, 9, 10				
	Other (spec.)	_	-	 				 				
	Cardiac Adult	_			·							
Cardiac	Cardiac Pediatric						 					
	Trans-esophageal (Cardiac)			-			···	 				
	Other (spec.)	1					· · · · · · · · · · · · · · · · · · ·					
Peripheral	Peripheral vessel	Р	Р	Р		ρ	Note 1	Note 2, 5, 6, 7, 9, 10				
Vessel	Other (spec.)					 	110001	11016 2, 3, 0, 7, 9, 11				

N= new indication; P= previously cleared by FDA K092159; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler
Note 1: B+M, B+PW, B+C, B+PD, B+CW, B+C+PW, B+PD+PW, B+C+M, Dual B, Dual B+C, Dual B+PD

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Note 10: ElastoScan

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD) Prescription Use (Per 21 CFR 801.109)

Indications for Use

(Division Sign-Off)
Division of Rediological Devices Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) No.:

Device Name: LF5-12 for use with ACCUVIX XG

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the h

	Clinical Application						des simultaneous	
General (Track I only)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic					<u> </u>	3-1	(5)00.7
	Fetal (See Note 3)	1						
	Abdominal	_						
	Intra-operative (See Note 6)	_			-			
	Intra-operative (Neuro.)	\top		l — –		-		
Fetal Imaging	Laparoscopic	\top						
& Other	Pediatric	Р	Р	- P		P	Note 1	Note 2, 5, 6, 7, 9, 10
	Small Organ (See Note 5)	P	P	q		P	Note 1	Note 2, 5, 6, 7, 9, 10
	Neonatal Cephalic	\top				 	110101	14016 2, 3, 6, 7, 9, 10
	Adult Cephalic	1	 	_				
4	Trans-rectal	+	 	 			-	
	Trans-vaginal	_ _						
	Trans-urethral							
	Trans-esoph. (non-Cardiac)					 	<u> </u>	
	Musculo-skel. (Convent.)	Р	Р	Р		P	Note 1	Note 2, 5, 6, 7, 9, 10
	Musculo-skel. (Superfic.)	P	ρ	Р		P	Note I	Note 2, 5, 6, 7, 9, 10
	Intra-luminal	1				 ` 	Hote I	Note 2, 3, 6, 7, 9, 10
	Other (spec.)	1						
	Cardiac Adult	 	_	-			·	
Cardiac	Cardiac Pediatric		1					
	Trans-esophageal (Cardiac)							
	Other (spec.)	1-						
Peripheral	Peripheral vessel	Р	Р	Р		Р	Note I	Note 2, 5, 6, 7, 9, 10
Vessel	Other (spec.)	_		\vdash			NOTE I	14016 2, 3, 6, 7, 9, 11

N= new indication; P= previously cleared by FDA K092159; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler
Note 1: B+M, B+PW, B+C, B+PD, B+CW, B+C+PW, B+PD+PW, B+C+M, Dual B, Dual B+C, Dual B+PD

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Note10: ElastoScan

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD) Prescription Use (Per 21 CFR 801.109)

Indications for Use

(Division/Sign-Off) Division of Radiological Devices Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) No.:

Device Name: LS5-13 for use with ACCUVIX XG

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the h

	: Diagnostic ultrasound in Clinical Application						des simultaneous B	
General Track Lonly)	Specific (Tracks I & III)	В	M	PWD	CMD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
<u> </u>	Fetal (See Note 3)				-			-
	Abdominal	\neg						<u> </u>
	Intra-operative (See Note 6)	Р	P	Р		Р	Note I	Note 8, 9
	Intra-operative (Neuro.)	P	Р	P		P	Note 1	Note 8, 9
Fetal Imaging	Laparoscopic	—	_			<u> </u>	7,010 1	1401.6 0, 9
& Other	Pediatric	P	P	Р		p	Note I	Note 8, 9
	Small Organ (See Note 5)	Р	Ρ	P		<u> </u>	Note I	Note 8, 9
	Neonatal Cephalic	P	Р	Р		P	Note 1	Note 8, 9
	Adult Cephalic					<u>-</u>	110001	14016 8, 9
	Trans-rectal							
	Trans-vaginal						-	
	Trans-urethral	1	_					·
•	Trans-esoph. (non-Cardiac)	\neg				<u> </u>	-	
	Musculo-skel. (Convent.)	P	Р	Р		Р	Note 1	Note 8, 9
	Musculo-skel. (Superfic.)	T P	Р	р		<u>р</u>	Note I	<u></u>
	Intra-luminal	_		-		<u> </u>	Note 1	Note 8, 9
	Other (spec.)	1		-				·
	Cardiac Adult	┪-						
Cardiac	Cardiac Pediatric					·	 	
	Trans-esophageal (Cardiae)	\top						
	Other (spec.)	1-			- -			- · · - · · · · · · · · · · · · · · · ·
Peripheral	Peripheral vessel	P	Р	Р		P	Nuta 1	N . C . C
Vessel	Other (spec.)	╅┶	<u> </u>	- 			Note 1	Note 5, 6, 9

N= new indication; P= previously cleared by FDA K093849; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+CW, B+C+PW, B+PD+PW, B+C+M, Dual B, Dual B+C, Dual B+PD

Note 2: Includes imaging for guidance of biopsy Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD) Prescription Use (Per 21 CFR 801.109)

Indications for Use

(Division Sign-Off)
Division of Radiological Devices Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) No.:

Device Name: P2-4BA for use with ACCUVIX XG

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the

	: Diagnostic ultrasound in Clinical Application						des simultaneous B-	
General (Track Lonly)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
	Fetal (See Note 3)							
	Abdominal	Р	₽	Ρ	P	р	Note I	Note 4, 7
	Intra-operative (See Note 6)	_				-		11000 4, 7
	Intra-operative (Neuro.)	\top						
Fetal Imaging	Laparoscopic							
& Other	Pediatric	_						
	Small Organ (See Note 5)							-
	Neonatal Cephalic					_		
	Adult Cephalic	P	P	P	P	Ρ	Note 1	Non 4. 7
	Trans-rectal .	 				<u> </u>	Note 1	Note 4, 7
	Trans-vaginal	1				· · · · · · · · · · · · · · · · · · ·		
	Trans-urethral							
	Trans-esoph. (non-Cardiac)					· · · · · · · · · · · · · · · · · · ·		
	Musculo-skel. (Convent.)	-					<u> </u>	· · · · · · · · · · · · · · · · · · ·
	Musculo-skel. (Superfic.)	+						
	Intra-luminal					<u> </u>		
	Other (spec.)							
	Cardiac Adult	Р	Р	ρ	Р	P	N	
Cardiac	Cardiac Pediatric	P	p	P	P	P	Note 1	Note 4, 7
	Trans-esophageal (Cardiac)	 	ٺ	- '	· · · · · ·		INULE	Note 4, 7
	Other (spec.)							
Peripheral	Peripheral vessel							
Vessei	Other (spec.)						<u></u>	

N= new indication; P= previously cleared by FDA K092159; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler
Note 1: B+M, B+PW, B+C, B+PD, B+CW, B+C+PW, B+PD+PW, B+C+M, Dual B, Dual B+C, Dual B+PD

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD) Prescription Use (Per 21 CFR 801.109)

Indications for Use

(Division Sign-Off) Division of Radiological Devices Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) No.:

Device Name: P3-8CA for use with ACCUVIX XG

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human hody

	Clinical Application						des simultaneous (3-	
General (Track Lonly)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							(10) 001/
	Fetal (See Note 3)	\lnot		_				
	Abdominal	Р	P	Р	Р	P	Note I	Note 4, 7
	Intra-operative (See Note 6)	_				 	110.01	14016 4, 7
	Intra-operative (Neuro.)		\vdash					
Fetal Imaging	Laparoscopic	\top					·	
& Other	Pediatric		\vdash					
	Small Organ (See Note 5)							
	Neonatal Cephalic							
	Adult Cephalic	Р	P	Ρ	Р	· ρ	Note I	Note 4, 7
	Trans-rectal	_				<u>'</u>	140101	14016 4, 7
	Trans-vaginal	<u> </u>	\vdash					
	Trans-urethral	_	 	-				· · · · · · · · · · · · · · · · · · ·
	Trans-esoph. (non-Cardiac)	_	 	-				
	Musculo-skel. (Convent.)		 					 -
	Musculo-skel. (Superfic.)		_					
	Intra-luminal							
	Other (spec.)	_				-		
	Cardiac Adult	Р	P	P	p	Р	Note 1	No. 4 7
Cardiac	Cardiac Pediatric	P	P	P	P	þ	Note I	Note 4, 7 Note 4, 7
	Trans-esophageal (Cardiac)		-					11016 4, 7
	Other (spec.)	_ _						
Peripheral	Peripheral vessel	_						
Vessel	Other (spec.)	┪-	 					

N= new indication; P= previously cleared by FDA K092159; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler
Note 1: B+M, B+PW, B+C, B+PD, B+CW, B+C+PW, B+PD+PW, B+C+M, Dual B, Dual B+C, Dual B+PD

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes intertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Indications for Use

Note 9: Panoramic imaging

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD) Prescription Use (Per 21 CFR 801.109)

Division of Radiological Devices Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) No.:

Device Name: P4-12 for use with ACCUVIX XG

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application	_ [Mode of C	peration (*inclu	des simultaneous B-	mode)
General (Track Lonly)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							(Speci)
	Fetal (See Note 3)	_						
	Abdominal	Р	Ъ	Р	P	P	Note I	Note 4, 7
	Intra-operative (See Note 6)					 		11010 4, 7
	Intra-operative (Neuro.)					 -		
Fetal Imaging	Laparoscopic	\top						
& Other	Pediatric	Р	Ρ	Р	Р	P -	Note 1	Note 4, 7
	Small Organ (See Note 5)	\top				 		11010 4, 7
	Neonatal Cephalic	Р	Р	Р	Р	P	Note (Note 4, 7
	Adult Cephalic	P	Р	P	P	P	Note I	Note 4, 7
	Trans-rectal					<u> </u>	110101	140(0 4, 7
	Trans-vaginal	_						
	Trans-urethral	1		_	_			· · · · · · · · · · · · · · · · · · ·
	Trans-esoph. (non-Cardiac)	_				 		
	Musculo-skel. (Convent.)	-						
	Musculo-skel. (Superfic.)	1					 	
	Intra-luminal	1		<u> </u>	,			<u> </u>
	Other (spec.)			-				.
	Cardiac Adult	Р	P	p	P	р	Note 1	Note 4, 7
Cardiac	Cardiac Pediatric	P	P	Р	P	P	Note I	Note 4, 7
	Trans-esophageal (Cardiac)		_		<u> </u>			11010 111
	Other (spec.)							· · ·
Peripheral	Peripheral vessel	1						·
Vessel	Other (spec.)					1		

N= new indication; P= previously cleared by FDA K101455; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+CW, B+C+PW, B+PD+PW, B+C+M, Dual B, Dual B+C, Dual B+PD

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and pen's in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD) Prescription Use (Per 21 CFR 801.109)

Division of Maulclogical Devices

Office of In Vitro Diagnostic Device Evaluation and Safety

Section 1.3, page 15

Indications for Use

510(k) No.:

Device Name: 3DC2-6 for use with ACCUVIX XG

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the b

	: Diagnostic ultrasound in Clinical Application						des simultaneous B-	
General (Track Lonly)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							 -
	Fetal (See Note 3)	Р	Р	Р		P	Note 1	Note 2, 7, 8
	Abdominal	Р	Р	Р		Р	Note I	Note 2, 7, 8
	Intra-operative (See Note 6)						1000	11010 2, 1, 8
	Intra-operative (Neuro.)				 -		-	
Fetal Imaging	Laparoscopic	1						, <u> </u>
& Other	Pediatric	P	Р	P		p	Note 1	Note 2, 7, 8
	Small Organ (See Note 5)		_			<u> </u>	Note 1	Note 2, 7, 8
	Neonatal Cephalic	\neg						· · · · · · · · · · · · · · · · · · ·
	Adult Cephalic	1						
	Trans-rectal		_					
	Trans-vaginal	\dashv						
	Trans-urethral	1		-				
	Trans-esoph. (non-Cardiac)	\neg				<u> </u>		
	Musculo-skel. (Convent.)	╅┤						
	Muscuto-skel. (Superfic.)							
	Intra-luminal	1						
	Other (spec.)				<u> </u>			
	Cardiac Adult	_						
Cardiac	Cardiac Pediatric							
	Trans-esophageal (Cardiae)	\top						
	Other (spec.)							
Peripheral	Peripheral vessel							
Vessel	Other (spec.)	\dashv						

N= new indication; P= previously cleared by FDA K093714; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+CW, B+C+PW, B+PD+PW, B+C+M, Dual B, Dual B+C, Dual B+PD

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD) Prescription Use (Per 21 CFR 801.109)

Indications for Use

(Division Sign-Off) Division of Radiological Devices Office of In Vitro Diagnostic Device Evaluation and Safety

Section 1.3, page 16

510K 103397

510(k) No.:

Device Name: V4-8 for use with ACCUVIX XG

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application				Mode of C	peration (*inclu	des simultaneous B	-mode)
General (Track I only)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							(-F)
	Fetal (See Note 3)	Р	Р	P		P	Note I	Note 2, 7, 8
	Abdominal	Р	Р	Р		Р	Note I	Note 2, 7, 8
	Intra-operative (See Note 6)	\neg		 	· · · · · · · · · · · · · · · · · · ·			11010 2, 7, 0
	Intra-operative (Neuro.)	\neg	_					
Fetal Imaging	Laparoscopic							
& Other	Pediatric	Р	P	Р		р	Note 1	Note 2, 7, 8
	Small Organ (See Note 5)	_					,,,,,,	11000 2, 7, 8
	Neonatal Cephalic							
	Adult Cephalic							**
	Trans-rectal					-		
	Trans-vaginal	╅				 -		
	Trans-urethral	\top				 -		
	Trans-esoph, (non-Cardiac)	\top						
	Musculo-skel. (Convent.)	_				 		-
	Musculo-skel. (Superfic.)		_	t		 		
	Intra-luminal				-			
	Other (spec.)					<u> </u>		
	Cardiac Adult	_			-	-		
Cardiac	Cardiac Pediatric				×	 		
	Trans-esophageal (Cardiac)					 		
_	Other (spec.)	\top				 		
Peripheral	Peripheral vessel	_						·
Vessel	Other (spec.)			ļ		 		

N= new indication; P= previously cleared by FDA K092159; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note I: B+M, B+PW, B+C, B+PD, B+CW, B+C+PW, B+PD+PW, B+C+M, Dual B, Dual B+C, Dual B+PD

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD) Prescription Use (Per 21 CFR 801.109)

Indications for Use

(Division Sign-Off) Division of Radiological Devices Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) No.:

Device Name: V5-9 for use with ACCUVIX XG

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application						des simultaneous B	
General (Track Lonly)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic						(4,5	(5)00.7
	Fetal (See Note 3)							
	Abdominal	\top		1				· · · · · · · · · · · · · · · · · · ·
	Intra-operative (See Note 6)	\top						
	Intra-operative (Neuro.)					 		· · · · · · · · · · · · · · · · · · ·
Fetal Imaging	Laparoscopic	-				 		<u></u>
& Other	Pediatric			<u> </u>	-			
	Small Organ (See Note 5)				·	<u> </u>		
	Neonatal Cephalic	1		 		 		
	Adult Cephalic	\top		t				·
	Trans-rectal	Р	Р	Ρ.		P	Note I	Note 2, 7, 8
	Trans-vaginal	Р	Р	Р		P	Note I	Note 2, 7, 8
	Trans-urethral			-		 	Aut I	14012 2, 7, 8
	Trans-esoph. (non-Cardiac)	1		 				
	Musculo-skel. (Convent.)	\top		İ				
	Musculo-skel. (Superfic.)			-		l		
	Intra-luminal	1		<u> </u>				
	Other (spec.)			!				
	Cardiac Adult					-		
Cardiac	Cardiac Pediatric	\dashv						
	Trans-esophageal (Cardiac)			t		<u> </u>		
	Other (spec.)					 		
Peripheral	Peripheral vessel	1		-				-
Vessel	Other (spec.)	1 -		 		 	 	

N= new indication; P= previously cleared by FDA K092159; E= added under Appendix E

Additional Comments:

- Color Doppler includes Power (Amplitude) Doppler
 Note 1: B+M, B+PW, B+C, B+PD, B+CW, B+C+PW, B+PD+PW, B+C+M, Dual B, Dual B+C, Dual B+PD
- Note 2: Includes imaging for guidance of biopsy
- Note 3: Includes intertility monitoring of follicle development
- Note 4: Color M-mode
- Note 5: for example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients
- Note 6: Abdominal organs and peripheral vessel
- Note 7: Tissue Harmonic Imaging (THI)
- Note 8: 3D imaging
- Note 9: Panoramic imaging

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD) Prescription Use (Per 21 CFR 801.109)

Indications for Use

(Division Sign-Off) Division of Radiological Devices Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) No.:

Device Name: V6-12 for use with ACCUVIX XG

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human had

	Clinical Application						des simultaneous L	
General (Track Lonly)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
	Fetal (See Note 3)		_					<u> </u>
	Abdominal						<u> </u>	
	Intra-operative (See Note 6)	1	<u> </u>			 		
	Intra-operative (Neuro.)							
Fetal Imaging	Laparoscopic							
& Other	Pediatric	Р	4	þ		p	Note I	Note 2, 5, 6, 7, 9
	Small Organ (See Note 5)	Р	Р	Р	·	Р	Note 1	Note 2, 5, 6, 7, 9
	Neonatal Cephalic							. 1,000 2, 5, 0, 7, 7
	Adult Cephalic	_						
	Trans-rectal							
	Trans-vaginal	┪			•	 		
	Trans-urethral							
	Trans-esoph. (non-Cardiac)		-			-		
	Musculo-skel. (Convent.)	Р	Р	Р		Р	Note I	Note 2, 5, 6, 7, 9
	Musculo-skel. (Superfic.)	Р	Ρ	Р		Р	Note I	Note 2, 5, 6, 7, 9
	Intra-luminal							
	Other (spec.)							
	Cardiac Adult					 		•
Cardiac	Cardiac Pediatric						-	· · · ·
	Trans-esophageal (Cardiac)							
	Other (spec.)					 		·
Peripheral	Peripheral vessel	Р	р	р		Р	Note 1	Note 5, 6, 7, 9
Vessel	Other (spec.)					 	.,,,,,,	11000 2, 0, 7, 9

N= new indication; P= previously cleared by FDA K092159; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler
Note 1: B+M, B+PW, B+C, B+PD, B+CW, B+C+PW, B+PD+PW, B+C+M, Dual B, Dual B+C, Dual B+PD

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Indications for Use

Note 9: Panoramic imaging

Concurrence of CDR11, Office of In Vitro Diagnostic Devices (OIVD) Prescription Use (Per 21 CFR 801.109)

Division of Magiological Devices

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) No.:

Device Name: CW2.0 for use with ACCUVIX XG

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application				Mode of O	peration (*inclu	des simultaneous B-	mode)
General (Track I only)	Specific (Tracks I & III)	B	М	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							(0),00,7
	Fetal (See Note 3)			_				
	Abdominal	7						
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
Fetal Imaging	Laparoscopie							
& Other	Pediatric			 	<u> </u>			
	Small Organ (See Note 5)							
	Neonatal Cephalic	_		<u> </u>				· · · · · · · · · · · · · · · · · · ·
	Adult Cephalic	1			Р	<u> </u>		<u></u>
	Trans-rectal			<u> </u>	<u> </u>	<u> </u>		
	Trans-vaginal							
	Trans-urethral	_			† — —	 		
	Trans-esoph. (non-Cardiac)	_						
	Musculo-skel. (Convent.)	_						
	Musculo-skel. (Superfic.)	_						
	Intra-luminal	\neg						
	Other (spec.)				<u> </u>		-	
	Cardiac Adult			_	Р			
Cardiac	Cardiac Pediatric	—			P	·		*****
	Trans-esophageal (Cardiac)				_		 	
	Other (spec.)					<u> </u>		
Peripheral	Peripheral vessel	1			P			
Vessel	Other (spec.)					 		

N= new indication; P= previously cleared by FDA K092159; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler
Note 1: B+M, B+PW, B+C, B+PD, B+CW, B+C+PW, B+PD+PW, B+C+M, Dual B, Dual B+C, Dual B+PD

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD) Prescription Use (Per 21 CFR 801.109)

Indications for Use

Division of Radiological Devices Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) No.:

Device Name: CW4.0 for use with ACCUVIX XG

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application				Mode of O	peration (*inclu	des simultaneous B-r	node)
General (Track Lonly)	Specific (Tracks I & III)	В	М	PWD	CMD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic	T^{-}						
	Fetal (See Note 3)						-	
	Abdominal	_						
	Intra-operative (See Note 6)			-				
	Intra-operative (Neuro.)							
Fetal Imaging	Laparoscopic	丁						·
& Other	Pediatric	1			P			
	Small Organ (See Note 5)	_ _	<u> </u>		-			
	Neonatal Cephalic	十一	1	<u> </u>				
	Adult Cephalic	╅	\vdash		P			 -
	Trans-rectal				<u> </u>		-	 -
	Trans-vaginal	十	\vdash					
	Trans-urethral			†			· · · · · · · · · · · · · · · · · · ·	<u>-</u>
	Trans-esoph. (non-Cardiac)		┝┈╴		-			
	Musculo-skel. (Convent.)					<u> </u>		
	Musculo-skel. (Superfic.)							
	Intra-luminal			1				<u> </u>
	Other (spec.)	\top	 				-	<u>.</u>
	Cardiac Adult	╅		<u> </u>	р			
Cardiac	Cardiac Pediatric				P		 	· · ··
	Trans-esophageal (Cardiac)		1	T			<u> </u>	
	Other (spec.)			<u> </u>				·-···
Peripheral	Peripheral vessel	1	$\overline{}$		P	<u> </u>		
Vessel	Other (spec.)						1	

N= new indication; P= previously cleared by FDA K092159; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler
Note 1: B+M, B+PW, B+C, B+PD, B+CW, B+C+PW, B+PD+PW, B+C+M, Dual B, Dual B+C, Dual B+PD

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD) Prescription Use (Per 21 CFR 801.109)

Indications for Use

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